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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,022	11/13/2001	Jamieson William Maclean Crawford	P-4523/15	1428
26253	7590	01/21/2004	EXAMINER	
BECTON, DICKINSON AND COMPANY 1 BECTON DRIVE FRANKLIN LAKES, NJ 07417-1880			HAYES, MICHAEL J	
			ART UNIT	PAPER NUMBER
			3763	8
DATE MAILED: 01/21/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/054,022

Applicant(s)

CRAWFORD ET AL.

Examiner

Michael J Hayes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 November 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a) because they fail to show the cap recited in claim 1. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant amended claim 1 to recite the assembly to initially have the cannula exposed and the shield in a proximal position. Claim 2, dependent from claim 1, requires a finger to engage the outer tube when the shield is in the distal position. The assembly is not enabled for having the shield stopping in the distal position after moving from the proximal position when the spring is released so that the finger's proximal face engages the distal end of the outer tube. There is nothing disclosed that would prevent the shield from sliding past the distal end of the outer tube. There is no relationship of

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elements that stops the finger's proximal face against the outer tube distal end after the spring is released.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over VAILLANCOURT (U. S. Patent No. 5,591,138) in view of GRABIS et al. (U. S. Patent No. 6,322,540) and SHAW (U. S. Patent No. 5,779,679). Vaillancourt discloses a needle assembly including a hub with an inner tube and outer tube connected at a proximal end, a cylindrical space between the tubes for a spring that biases a shield with a finger 39 to cover the needle when extending. Vaillancourt does not disclose applying an inwardly directed force to actuate the shield (Vaillancourt uses a rotating motion) nor a cap to enclose the needle. Grabis teaches the actuation of the spring by applying an inwardly directed force on a finger projecting outwardly from the shield. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Grabis in the invention of Vaillancourt in order to achieve simple one-handed actuation. Shaw teaches the use of a cap to cover an exposed needle when the needle is exposed prior to use (3:12-15). It would have been obvious to one of ordinary skill in the art at the time of the invention to use a cap to cover an exposed needle to prevent injury.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over VAILLANCOURT and GRABIS as applied to claim 1 above, and further in view of SHAW (U. S. Patent No. 5,779,679). Vaillancourt and Grabis disclose the claimed invention except for radially extending wings. Shaw teaches the use of radially extending wings 18 for handling. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Shaw in the device of Vaillancourt and Grabis in order to use the needle assembly safely.

Response to Arguments

Applicant generally argues that the devices of Vaillancourt and Grabis operate differently and one would have no motivation to combine and such a combination is difficult to envision and retain an operative device. The examiner disagrees because Grabis teaches the use of a spring actuated by inwardly directed forces in order to facilitate one-handed operation. The predictability of the mechanical arts suggests that the modification of Vaillancourt from a rotatable spring lock to a button depressed spring lock would be operable. One of ordinary skill in the art would be able to follow the disclosure of Grabis to incorporate the unlocking by depressing the finger instead of rotating it.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Haber et al. (U. S. Patent No. 4,813,426) shows a blood collection needle with shield. Sudnak (U. S. Patent No. 4,894,055) shows a biased extending shield for a needle.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler, can be contacted at (703) 308-3552. The fax number for submitting official papers is (703) 872-9306.

mjh
19 January 2004

A handwritten signature in black ink, appearing to read "MJ Hayes", with a stylized flourish at the end.

MICHAEL J. HAYES
PRIMARY EXAMINER